


<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>09871/0200096-US0</b>	
	Application Number <b>10/676,327-Conf. #6524</b>	Filed <b>September 30, 2003</b>	
	First Named Inventor <b>Minoru Takatsuka et al.</b>		
	Art Unit <b>3763</b>	Examiner <b>T. J. Stigell</b>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 45%;"> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>44,528</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> </div> <div style="width: 50%; text-align: center;">         _____        Signature         _____        Thomas J. Bean        Typed or printed name         _____        (212) 527-7700        Telephone number        _____        March 21, 2007        Date     </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<input type="checkbox"/> *Total of <u>1</u> forms are submitted.			



a drive force, a transmission mechanism part for transmitting the drive force to the push member, and a control unit for controlling movement of the push member by controlling the drive motor. The control unit controls the drive motor to move the push member to gradually increase an injection speed of the anesthetic in the beginning of the injection and to move the push member to inject the anesthetic in a constant injection speed after a predetermined time has elapsed.

Hodosh discloses a fluid dispenser for administering an anesthetic that includes a rack member 58 to press and move a piston 16 in a carpule 12 in order to inject an anesthetic from the carpule 12 through a needle 42. A variable speed motor 202 drives the rack member 58 by means of a drive mechanism 204, and under the control of a microprocessor 200. Hodosh does not disclose that the microprocessor 200 gradually increases the injection speed until it reaches a constant speed after a predetermined time.

As asserted in the Responses filed to the final Office Action of September 21, 2006 and to the Office Action of March 28, 2006, Hodosh does not disclose or suggest a control unit that gradually increases the injection speed until it reaches a constant speed after a predetermined time, as set forth in independent claims 1 and 15. The Examiner responded in the final Office Action by stating that this limitation is met by the embodiment of Hodosh's dispenser disclosed at FIG. 9 and at column 10, lines 20 - 24. Applicants respectfully disagree.

At column 10, lines 20-24, Hodosh discloses that, after pressing button 208 to begin the flow of anesthetic, "the anesthetic flows slowly [at first] in order to overcome the breakaway force of the piston 16. After 1 to 2 seconds, the microprocessor 200 instructs the motor 202 to drive mechanism 204 at a speed which corresponds to the desired injection pressure."

The interval taken to overcome the breakaway force of the piston is brief, after which the microprocessor commands an injection speed that will produce the desired, single injection pressure. Applicants submit that this will, at best, form an initial trickle of anesthetic which is followed by a step change rather than a gradual change to speed corresponding to the single desired injection pressure. This initial trickle is simply a "bleed-off" that occurs when an incompressible

fluid, such as an anesthetic, is compressed in a container provided with one outlet, which in this case is the annular stem portion 44 that conducts anesthetic to the needle. The initial “bleed-off” is just that, it is not directed to achieve a specified injection speed or pressure, but is a priming step.

With regard to claim 15, the Responses to the Office Actions of September 21, 2006 and March 28, 2006 further assert that Hodosh fails to disclose or suggest an additionally-provided sound output unit configured to output a buzzing or melodic sound under the control of the control unit during the injection of the anesthetic. The Examiner responded in the final Office Action by stating that this limitation is inherently met by Hodash’s motor 202, which would normally produce a buzzing noise during operation. Applicants respectfully disagree.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP § 2112 (IV). Applicants submit that just the fact that Hodosh discloses a motor is not sufficient to establish the inherency that the device necessarily outputs a buzzing sound perceivable by the user. For example, one or more of the housing and the motor may be insulated to prevent the output of noise from the motor. Just because a motor may be capable of producing a sound, does not establish that it is inherent that Hodosh’s device outputs a sound as claimed.

In the Advisory Action of February 12, 2007, the Examiner finds the above arguments to be unpersuasive. The Examiner suggests, with regard to the arguments made for each of claims 1 and 15, that as the “bleed off” step results in a dispensing of fluid, it necessarily “[qualifies as producing] an injection speed.” With regard to the additional arguments made for claim 15, the Examiner suggests that “the motor will make a buzzing sound even if measures are taken to suppress the sound,” as in “the vast majority of times the motor will still make a discernible sound.” Applicants respectfully disagree with these positions.

Applicants’ arguments with regard to Hodosh’s “bleed off” step are not directed to suggest that the dispensing of fluid occurs without some characteristic injection speed, but rather that this speed is not controlled by the microprocessor 200 to gradually increase to a constant speed after a

predetermined time. For example, as described at column 10, lines 20 - 24 of Hodosh, microprocessor 200 provides an instruction to motor 202 only after the “bleed off” period of 1 to 2 seconds has been completed. In other words, as disclosed by Hodosh, no control is exercised by the microprocessor 200 during the “bleed off” period. More specifically, Hodosh provides no teaching or suggestion indicating that the microprocessor 200 controls the motor 202 to gradually increase injection speed during the “bleed off” period.

This element of Applicants’ claimed invention provides a significant benefit. By controlling the injection speed to increase gradually to a constant speed, the perception of pain that is felt by a patient at the beginning of an injection can be reduced by an initially-low injection speed, and gradually increased to a constant speed that is higher than one tolerated by a patient as an initial injection speed (see, e.g., page 25, lines 7 - 20 of Applicants’ specification). As a result, in addition to reducing the patient’s perceptions of pain, injection times can also be reduced. Applicants note that Hodosh does not recognize or speak to any need for achieving these benefits.

Further in regard to claim 15, Applicants repeat their previous arguments to suggest that it is not inherent that the device disclosed by Hodosh must be configured in such a manner as to provide an audible buzzing sound that is produced by the motor 202. In addition, Applicants note that claim 15 separately claims a sound output unit and a claimed drive motor, and claims the control of the drive motor and control of the sound output unit as distinct control functions of the claimed control unit. Applicants suggest that to interpret claim 15 as suggested by the Examiner to permit the claimed sound output unit to have identity with the claimed drive motor would raise issues as to “double inclusion” and claim indefiniteness. As claims are generally construed in a manner that preserves validity, Applicants respectfully submit that for this additional reason, the motor 202 of Hodosh does not read on Applicants’ claimed sound output unit.

For the aforementioned reasons, Hodosh fails to teach or suggest all of the features of the present invention as set forth in independent claims 1 and 15. Claims 2, 11 - 13, 16 and 17 are dependent on independent claims 1 and 15 and are therefore also allowable for at least the same reasons.

Applicants respectfully submit that pending claims 1 - 19 are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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